

REMARKS

The present application includes pending claims 1-4, 6-9 and 12-20, all of which have been rejected.

I. Provisional Nonstatutory Obviousness-Type Double Patenting Rejection

Claims 1-4, 6-9 and 12-20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-10, 13-16 and 19-21 of copending Application No. 10/962,019 (the "'019 application"). The '019 application is a continuation-in-part of the present application and, as such, was filed after the present application.

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

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If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer.

See Manual of Patent Examining Procedure (MPEP) at § 804(I)(B)(1).

The present application was filed April 2, 2004, while the co-pending application was filed October 8, 2004. Thus, the present application was filed earlier than the co-pending application. After consideration of the arguments below with respect to the 35 U.S.C. § 102 rejection, the provisional nonstatutory obviousness-type double patenting rejection should be the only remaining rejection with respect to the present application. The Applicant respectfully

submits that pursuant to MPEP at § 804(I)(B)(1), the provisional double patenting rejection should therefore be withdrawn.

II. Rejection Under 35 U.S.C. § 102(e)

Claims 1-4, 6-9 and 12-20 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,490,475 ("Seeley"). The Applicant respectfully traverses this rejection for at least the reasons previously discussed during prosecution and the following:

"A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in **a single prior art reference.**" *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). "The **identical** invention must be shown in as complete detail as is contained in ... the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

Claim 1 recites, in part, "a tracking system for measuring one or more locations on said instrument using said sensor and said plurality of fiducials in closed form registration to calibrate said instrument, wherein said tracking system compares measurements from said instrument with a model for said instrument **to determine a variation based on deformity of the instrument**, said tracking system adjusting tracking of said instrument based on said variation."

Seeley, however, does not describe, teach or suggest determining a variation based on **deformity of an instrument**. Seeley does disclose a "distorted tool image." See Seeley at column 5, lines 3-5. However, there is nothing in Seeley that describes, teaches or suggests determining a variation based on deformity, such as caused by repeated high stress encountered during surgery (*see* present application at [0013]), of an instrument. That is, Seeley does not

describe, teach or suggest “a tracking system for measuring one or more locations on said instrument using said sensor and said plurality of fiducials in closed form registration to calibrate said instrument, wherein said tracking system compares measurements from said instrument with a model for said instrument to determine a variation based on deformity of the instrument, said tracking system adjusting tracking of said instrument based on said variation,” as recited in claim 1.

The Office Action cites Seeley at Abstract and column 4, lines 26-30 as disclosing these limitations. However, there is nothing these cited portions, nor the remainder, of Seeley that describes, teaches or suggests determining a variation based on **deformity of an instrument**. Thus, for at least these reasons, the Applicant respectfully requests reconsideration of the claim rejections.

Next, claim 1 also recites, in part, “wherein said tracking system further comprises a feedback mechanism used during surgical navigation to determine accuracy of tracking of the instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a certain tolerance and recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.” The Office Action cites Seeley at column 6, lines 9-42 and column 9, lines 4-25 as disclosing these limitations. *See* June 26, 2008 Office Action at page 4. As such, the Applicants will address each of these cited portions of Seeley.

First, Seeley states the following:

A table of position correction factors or characteristics may be compiled for one or more of the tracking elements to correct for the effects of electromagnetic shunting or other forms of interference with the generator or receiver which may occur when

positioned in a region near to the body of the fluoroscope. This allows a magnetic tracking element to be placed quite close to the imaging assembly or other conductive structure and achieve high position tracking accuracy or resolution. In particular, one or more tracking elements may be mounted directly on the fluoroscope to define camera and imaging parameters relative to another tracker which may move with the patient or with a tool.

See Seeley at column 6, lines 23-36. This portion of Seeley broadly discloses a compiled table of factors to correct for the effects of electromagnetic shunting or other forms of interference. Neither this, nor the rest of Seeley at column 6, lines 9-42, however, describes, teaches or suggests “wherein said tracking system further comprises a **feedback mechanism used during surgical navigation** to determine accuracy of tracking of the instrument by **comparing tracked versus actual instrument position** to determine whether positional accuracy is within a **certain tolerance** and **recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.**”

Next, Seeley also discloses the following:

The equipment and procedure has two components, a first component provided by a tracking assembly which determines position of a fluoroscope calibration fixture relative to one or both of the tool and patient body, and a second component provided by a processor operating on each image that characterizes or models the geometry of the camera and performs all subsequent processing. This is done by providing a calibration fixture that contains an array of markers, which is either tracked as a rigid unit or affixed to the camera, while the imaged position of the markers in each fluoroscope shot serves to characterize the imaging geometry so as to allow correction of imaged features at measured distances from the camera, and permit registration of successive images in different poses.

Id. at column 9, lines 12-25. Thus, this portion of Seeley discloses that a calibration fixture having an array of markers is tracked. The imaged position of the markers characterizes the

imaging geometry to allow correction of the imaged features, and permits registration of successive images in different poses. Neither this, nor the rest of Seeley at column 9, lines 4-25, however, describes, teaches or suggests “wherein said tracking system further comprises a **feedback mechanism used during surgical navigation** to determine accuracy of tracking of the instrument by **comparing tracked versus actual instrument position** to determine whether positional accuracy is within a **certain tolerance** and **recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.**”

Seeley also discloses “integrat[ing] tracked tool position with the fluoroscope shot.” *See id.* at column 13, lines 54-56. Further,

[D]uring an ongoing procedure, the tracking assembly may track tool movement relative to the patient, and a processor controls the tracking and determines from the position of the tool when it is necessary to redraw the integrated display using the above-describe image distortion transformations to correctly situate the displayed tool in a position on a new image.

Id. at column 14, lines 26-33. As Seeley explains, the “process of camera calibration is a process of applying actual coordinates as determined by the tracking system and marker positions, and image coordinates as seen in the fluoroscopic marker images, to model a camera for the image.” *See id.* at column 14, lines 34-38.

As shown above, Seeley discloses “applying actual coordinates... and image coordinates... to model a camera for the image.” However, it does not disclose **comparing** a tracked position to an actual position. The Office Action has not shown where Seeley describes, teaches or suggests **comparing tracked versus actual instrument position** to determine whether positional accuracy is within a certain tolerance. Seeley does not describe, teach or suggest “wherein said tracking system further comprises a **feedback mechanism used during**

surgical navigation to determine accuracy of tracking of the instrument by **comparing tracked versus actual instrument position** to determine whether positional accuracy is within a **certain tolerance,**” as recited in claim 1.

Further, the Office Action has not shown where Seeley discloses “**recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.**” Indeed, the Applicants respectfully submit that this particular limitation is not found in Seeley.

For at least these reasons, the Applicant respectfully request reconsideration of the rejection of claims 1-4 and 6-7.

Claim 2 recites “wherein said plurality of fiducials comprise at least one of an indentation and a groove.” The Office Action has not shown where Seeley discloses a fiducial that includes an indentation or a groove. Indeed, the Office Action does not even recite “indentation” or “groove.” Instead, the Office Action merely cites a portion of Seeley, namely column 5, lines 32-54 (*see* June 26, 2008 Office Action at page 4), that discloses the following: “This provides a direct registration of the preoperative data to tracking coordinates without requiring the surgeon to place and image fiducials....” There is nothing in this cited portion of Seeley that describes, teaches or suggests a fiducial that includes an indentation or groove. Thus, for at least this additional reason, the Applicant respectfully requests reconsideration of the rejection of claim 2.

Independent claim 8 recites, in part, “comparing said model of said instrument with a mathematical model of said instrument to determine a variation based on deformity of the instrument; ... obtaining feedback during surgical navigation to determine accuracy of tracking

of said instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a certain tolerance; and recalibrating said instrument during surgical navigation if the positional accuracy is outside the certain tolerance.” For at least the reasons discussed above with respect to claim 1, the Applicants respectfully request reconsideration of the rejection of claims 8-9 and 12-13.

Independent claim 14 recites, in part, “comparing said model of said instrument with a mathematical model of said instrument to determine a variation based on deformity of the instrument; ... obtaining feedback during the image-guided operation to determine accuracy of tracking of said instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a certain tolerance; and recalibrating said instrument during image-guided operation if the positional accuracy is outside the certain tolerance.” For at least the reasons discussed above with respect to claim 1, the Applicants respectfully request reconsideration of the rejection of claims 14-20.

III. Conclusion

In general, the Office Action makes various statements regarding the pending claims and the cited references that are now moot in light of the above. Thus, the Applicant will not address such statements at the present time. However, the Applicant expressly reserves the right to challenge such statements in the future should the need arise (e.g., if such statement should become relevant by appearing in a rejection of any current or future claim).

The Applicant respectfully requests reconsideration of the claim rejections for at least the reasons discussed above. If the Examiner has any questions or the Applicant can be of any assistance, the Examiner is invited to contact the undersigned attorney.

Application No. 10/817,652
Response Under 37 C.F.R. § 1.116
July 16, 2008

The Commissioner is authorized to charge any necessary fees, or credit any overpayment
the Deposit Account of GTC, Account No. 07-0845.

Respectfully submitted,

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